CDC Human Subjects Adverse Event Report

(To Be Filled Out By Lead CDC Investigator)

An adverse event (AE) is defined as a physical injury to human research participants. Serious events (i.e., life threatening) should be reported to the IRB within 24 hours. Less serious injuries must be reported to the IRB within two weeks of their occurrence.

Please complete and sign this form. Submit to the Human Subjects Manager, Mark Long, at Mailstop D-50. Following review by the IRB, the IRB Chair will notify the Deputy ADS, who will notify OPRR in writing of the event and the corrective actions taken.

CDC Investigator: _____

Protocol Number: _____

Participant's I.D. (if available): _____

Date of Event: _____

Date First Known to You: _____

Name of Drug, Device or Procedure: _____

Describe in detail the nature of the AE and timing of the event (attach addendum if necessary):

The likelihood the event was caused by the study is:

_____ Probable _____ Possible _____ Unlikely _____ Definitely unrelated

Impact on participant (Check all that apply):

_____ Participant died
_____ Required follow-up treatment
_____ Resulted in prolonged hospitalization
_____ Participant remains on study
_____ Resulted in disability
_____ Required first aid
_____ Attention beyond first aid

Did investigator report this AE to? (Check all that apply)

_____ Co-investigator _____ FDA _____ Data Safety Monitoring Board

Describe corrective action taken by study investigator: (Check all that apply)

_____ Stop enrollment of new participants
_____ Halt the study
_____ Change data management/ coding procedures
_____ Form committee to review procedures
_____ Other (Please Comment)

Does this event require revision to the (YES or NO):	_____ Protocol	_____ Consent Form
If yes, please submit amendment (CDC form 1252), revised protocol and consent form.		
Signature of lead CDC investigator: _____ **Date:** _____ _		
Printed name of lead CDC investigator: _____ **Phone:** _____ __		

Approvals (Signature and Position Title)	**Date:**	**Remarks:**
Branch Chief:		
Division Director:		
CIO HSC:		